

Remarks/Arguments:

Introduction

Claims 1-9 and 11-13 are pending. Claims 2, 4, 5, 9-11 are withdrawn from consideration.

Independent claim 1 is directed to a stent/graft composite device formed from a flat preformed planar strip and stent assembly. The stent/graft composite device comprises an elongate preformed non-textile planar strip of polymeric graft material having a first exterior surface and a second opposed luminal surface; and a planar stent attached onto one of said opposed flat exterior or luminal surfaces of said strip to form said flat strip assembly, said strip assembly being helically wound into a continuous tubular structure. (emphasis added)

Section 103 Rejections

Claims 1, 3, 6-8, 12 and 13 are rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over U.S. Patent No. 6,352,561 to Leopold et al. (hereinafter "Leopold") in view U.S. Patent No. 6,165,210 to Lau et al. (hereinafter "Lau"). Applicants respectfully traverse.

Leopold is directed to a stent-graft 106. (Leopold, column 6, lines 37-38; FIG. 3). The stent-graft 106 of Leopold includes a stent 126, a luminal graft 124 and an outer covering or tape member 128. (Leopold, column 9, lines 9-15). The stent 126 is formed by helically winding a wire around a mandrel. (Leopold, column 10, lines 63-65). Leopold then specifically teaches that the helically wound wire is heated while the wire is on the mandrel to set the shape, e.g., tubular stent shape, of the so-formed stent. (Leopold, column 10, lines 65-67). Thus, Leopold specifically teaches that its tubular stent 106 is to be formed by winding the stent wire itself about the mandrel, and the so-formed tubular stent 106 does not yet have its luminal graft 124 or its outer tape member 128.

Leopold also forms its luminal graft 124 independently from its stent 106. (Leopold, column 11, lines 45-49). Leopold then specifically teaches that its luminal, tubular graft 124 is placed over a mandrel. (Leopold, column 11, lines 9-15). Leopold then teaches that its formed tubular stent 106 is placed over the tubular graft 124 so that both tubular devices are disposed over this mandrel. (Leopold, column 11, lines 49-53).

Finally, Leopold then wraps its tape member 28 over the exterior portions of the stent 106. (Leopold, column 11, lines 54-57). Leopold then places the mandrel into an oven to form its stent-graft 106. (Leopold, column 11, line 66, to column 12, line 7).

Thus, Leopold independently forms a tubular stent 106 and a tubular luminal graft 124, and its tape member 128 is to helically wrapped over these tubular components to form its tubular stent 106.

Such teachings of Leopold, however, are in direct contrast to the present invention. For example, Leopold fails to teach or suggest, *inter alia*, an elongate preformed non-textile planar strip of polymeric graft material, a planar stent attached to the planar graft material to form a flat strip assembly, which is subsequently wound to form the inventive stent graft.

As the Examiner acknowledges that Leopold fails to teach or suggest, *inter alia*, a planar stent assembly, the Examiner applies Lau, in particular FIGS 6, 7, 9 and 10 of Lau. Lau does teach that its stent structure 200, 202 of FIGS. 6 and 7 may be formed from a flat sheet. (Lau, column 13, lines 19-20). Lau, however, specifically teaches that its preformed strips of stent materials are to be wound over a mandrel. (Lau, column 14, lines 42-51). After Lau's preformed strips of stent material are helically wound over a mandrel, then its outer tubular graft or sleeve 217 is slipped over the helically wound stent 214. (Lau, column 14, lines 52-53; FIG. 10). Indeed, Lau specifically teaches throughout its patent that its tubular stent is to be first formed and then its graft layer is to be placed or formed over the tubular stent. (See, e.g., Lau, column 26, lines 48-58; column 27, lines 21-23; etc.).

Thus, Lau fails to teach or suggest, *inter alia*, an elongate preformed non-textile planar strip of polymeric graft material, a planar stent attached to the planar graft material to form a flat strip assembly, which is subsequently wound to form the inventive stent graft.

Accordingly, Lau fails to cure the deficiencies of Leopold.

In establishing a *prima facie* case of obviousness, the cited references must be considered for the entirety of their teachings. *Bausch & Lomb, Inc. v. Barnes-Hind, Inc.*, 230 U.S.P.Q. 416, 419 (Fed. Cir. 1986). It is impermissible during examination to pick and choose from a reference only so much that supports the alleged rejection. *Id.* It is only through hindsight reconstruction and selective picking and choosing while ignoring divergent teachings does the Examiner attempt to reach the present invention through the combination of Leopold and Lau. It is also well established, however, that hindsight reconstruction of a reference does not present a *prima facie* case of obviousness, and any attempt at hindsight reconstruction using Appellant's disclosure is strictly prohibited. *In re Oetiker*, 24 U.S.P.Q.2d 1443, 1445-46 (Fed. Cir. 1993). Such hindsight reconstruction by the Examiner is clear as both Leopold and Lau individually fail to teach or suggest a planar stent and graft strip assembly.

Therefore, Leopold and Lau, individually or in combination, fail to teach or suggest, *inter alia*, an elongate preformed non-textile planar strip of polymeric graft material, a planar stent attached to the planar graft material to form a flat strip assembly, which is subsequently wound to form the inventive stent graft, as set forth in independent claim 1.

Reconsideration and withdrawal of the rejection of claims 1, 3, 6-8, 12 and 13 under 35 U.S.C. §103(a) are respectfully requested.

Accordingly, Applicant submits that claims 1, 3, 6-8, 12 and 13 are therefore in condition for allowance.

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Summary

Therefore, Applicant respectfully submits that independent claim 1, and all claims dependent therefrom, are patentably distinct. This application is believed to be in condition for allowance. Favorable action thereon is therefore respectfully solicited. Upon indication of allowable subject matter, reentry and allowance of the withdrawn claims are respectfully requested.

Should the Examiner have any questions or comments concerning the above, the Examiner is respectfully invited to contact the undersigned attorney at the telephone number given below.

No fee is believed to be due with this response. The Commissioner, however, is hereby authorized to charge payment of any additional or required fees associated with this communication, or credit any overpayment, to Deposit Account No. 08-2461. Such authorization includes authorization to charge fees for extensions of time, if any, under 37 C.F.R. § 1.17 and also should be treated as a constructive petition for an extension of time in this reply or any future reply pursuant to 37 C.F.R. § 1.136.

Respectfully submitted,

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